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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,038	10/19/2005	Luciano Adorini	59756CON(49949)	8321

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EXAMINER	
GOON, SCARLETT Y	
ART UNIT	PAPER NUMBER
1623	
MAIL DATE	DELIVERY MODE
08/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,038	ADORINI ET AL.	
	Examiner	Art Unit	
	SCARLETT GOON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36,47,64,78,80,82,85,89-91,98,99,101 and 102* is/are pending in the application.

4a) Of the above claim(s) *4, 6, 9-11, 14, 16, 18-20, 22-24, 26-36, 47, 64, 78, 80, 82, 85 and 89-91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7,8,12,13,15,17,21,25,98,99,101 and 102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *19 October 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed on 19 October 2005 in which claims 37-46, 48-63, 65-77, 79, 81, 83, 84, 86-88, 92-97, 100 and 103 were cancelled, and claims 21, 24, 34, 36, 47, 64, 78, 80, 82, 85, 89, 91, 98 and 101 are currently amended, is again acknowledged.

Claims 1-36, 47, 64, 78, 80, 82, 85, 89-91, 98, 99, 101 and 102 are pending in the instant application.

Priority

This application is claiming the benefit of prior-filed U.S. provisional application no. 60/466,638 filed on 30 April 2003 under 35 U.S.C. 119, 120, 121, or 365(c). Copendency between the current application and the prior provisional application is required. Since the applications are not copending, the benefit claim to the prior-filed nonprovisional application is improper. Applicant is required to delete the reference to the prior-filed application from the first sentence(s) of the specification, or the application data sheet, depending on where the reference was originally submitted, unless applicant can establish copendency between the applications. Thus, the priority date of the instant application is deemed to be its filing date on 19 October 2005.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-33, 98, 99, 101 and 102 in the reply filed on 27 April 2009 is acknowledged. The traversal is on the ground(s) that

the subject matter of the different groups represents different embodiments of a single inventive concept for which a single patent should issue. This is not found persuasive because, as indicated in the Election/Restriction requirement dated 23 February 2009, the inventions of Groups I and II, I and III and I and IV are separate and distinct, related as product and process of use. See the Restriction Requirement page 3. As noted in MPEP § 806.05(h), the criteria for distinct inventions is that (2) the product as claimed can be used in a materially different process of using that product. In the instant case, the composition comprising a vitamin D3 compound can be used to treat hypertension and osteoporosis -- which are materially different from the process as claimed, for treating a vitamin D3 associated state, a urogenital disorder, and inhibiting transplant rejection. Furthermore, the inventions of Groups II, III and IV are unrelated because each invention involves different reagents and different steps, also resulting in different outcomes. Therefore, the inventions of Groups I-IV are seen to be separate and distinct inventions properly restricted from each other.

Applicants additionally traverse on the grounds that a sufficient search and examination with respect to the subject matter of all the claims can be made without a serious burden. This argument is not persuasive because the inventions would require different fields of search. The search field for a composition is non-coextensive with the search field for a method of treating a patient employing the same composition. A reference to the composition herein would not necessarily be a reference to the method of treatment herein under 35 USC § 103 because a search indicating the process or method is novel or unobvious would not extend to a holding that the product itself is

novel or unobvious whereas a search indicating that the product is known or would have been obvious would not extend to a holding that the process or method is known or would have been obvious. Note that the search is not limited to patent files. Thus, an undue burden on the Office is seen for the search of all inventions herein.

The requirement is still deemed proper and is therefore made FINAL.

Claims 34-36, 47, 64, 78, 80, 82, 85 and 89-91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 27 April 2009.

Claims 4, 6, 9-11, 14, 16, 18-20, 22-24 and 26-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 27 April 2009.

Claims 1-3, 5, 7, 8, 12, 13, 15, 17, 21, 25, 98, 99, 101 and 102 will be examined on its merits herein.

Information Disclosure Statement

The information disclosure statement (IDS) dated 19 October 2005 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. Accordingly, it has been placed in the application file and the information therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5, 7, 8, 13, 15, 21, 98, 99, 101 and 102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "X_1 is H_2 or CH_2" in claim 1 renders the claims herein indefinite. As X_1 is connected to a double bond, it is unclear how a double bond could be connected to H_2 and still be chemically accurate as it would exceed the valency limit for a hydrogen. The recitation is further unclear as H_2 generally stands for molecular hydrogen, e.g. H-H. Thus, it is unclear how H_2 could be connected to anything else without exceeding its valency limit.

The recitation "vitamin D3 associated state" in claims 99, 101 and 102 render the claims herein indefinite. The recitation of "associated" is not clearly defined in the specification, and therefore does not set forth the metes and bounds of the phrase "vitamin D3 associated state". WordNet 2.0 online teaches that "associated" means "related to or accompanying" (PTO-892, Ref. U). Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to "a disease associated with vitamin D3" herein. Thus, it is unclear and indefinite as to how the "vitamin D3 associated state" herein is encompassed thereby.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Section [0001]

Claims 1-3, 5, 7, 8, 12, 13, 15, 17, 21, 25, 98, 99, 101 and 102 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by WIPO publication WO/2004/098522 to Adorini *et al.* (PTO-892, Ref. N).

Adorini *et al.* disclose Gemini vitamin D3 compounds and methods for using the compounds to treat vitamin D3 associated states. Gemini vitamin D3 compounds include the structure denoted as compound (3) (p. 21). The compound is comprised in a pharmaceutical composition in an effective amount and also includes a

pharmaceutically acceptable carrier (p. 47, lines 20-24). For treatment of a vitamin D3 associated state in a subject, the composition is administered in an effective amount (p. 26, lines 22-25). Although dosages may vary depending on the particular indication, route of administration and subject, the Gemini vitamin D3 compounds are administered at a concentration of about 0.001 μg to about 100 μg/kg of body weight (p. 27, lines 8-10). Adorini *et al.* further disclose a packaged formulation comprising the vitamin D3 composition and instructions for its use in the treatment of a vitamin D3 associated state (p. 122, claim 101).

The disclosure of Adorini *et al.* anticipates claims 1-3, 5, 7, 8, 12, 13, 15, 17, 21, 25, 98, 99, 101 and 102.

Section [0002]

Claims 1-3, 5, 7, 8, 12, 13, 15, 17, 21, 25, 98, 99, 101 and 102 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by WIPO publication WO/2005/030223 to Colli (PTO-892, Ref. O).

Colli discloses vitamin D compounds and methods of using the compounds to treat bladder dysfunction. One such vitamin D compound is denoted as compound (2) (p. 25). In a method of treating bladder dysfunction, the vitamin D compound is administered in an amount effective to treat the dysfunction (p. 6, lines 16-19). The vitamin D compound is administered to the subject using a pharmaceutically-acceptable formulation (p. 41, lines 24-29). A therapeutically effective amount may range from about 0.001 to 30 μg/kg of body weight (p. 8, lines 7-33). Colli further discloses a kit

containing the vitamin D compound together with instructions directing administration of the vitamin D compound to a patient in need of treatment of bladder dysfunction (p. 6, lines 20-24).

The disclosure of Colli anticipates claims 1-3, 5, 7, 8, 12, 13, 15, 17, 21, 25, 98, 99, 101 and 102.

Section [0003]

Claims 1-3, 5, 7, 8, 12, 13, 15, 17, 21, 25, 98, 99, 101 and 102 are rejected under 35 U.S.C. 102(a) as being anticipated by journal publication by Maehr *et al.* (PTO-892, Ref. V).

Maehr *et al.* disclose calcitriol derivatives with two different side chains at C-20. The compounds include (2a), (2b), (3a) and (3b) (p. 6476). The compounds were administered to mice at a dose as high as 100 μg/kg (p. 6477, column 1, bridging paragraph; Table 2).

With regards to instant claims 101 and 102, it is noted that Maehr *et al.* do not explicitly disclose instructions for the use of the composition. However, a composition with a set of instructions is regarded as a kit. Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004).

Compound (2b) and its administration to mice at a concentration of 100 μg/kg anticipates instant claims 1-3, 5, 7, 8, 12, 13, 15, 17, 21, 25, 98, 99, 101 and 102.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

SCARLETT GOON
Examiner
Art Unit 1623